March 8, 1974

Dr. Channing H. Lushbough
Citizens' Commission on Science, Law and the Food Supply
Rockefeller University
1230 York Avenue at 66th Street
New York, New York 10021

Dear Dr. Lushbough,

I would like to take advantage of the opportunity that you have offered to introduce a substitute version of the summary of my comments for those that appear on page 9. Also as you may not have yet an opportunity to read the final draft of my paper for the NAS Forum, I am enclosing a copy herewith. Actually, I think I have touched in a general way on most of the points brought up in your last paragraph on page 14. I do not think we lack for broad philosophical principles or general guidelines at this point. What we certainly do need is much more precise analysis and the methodology therefore.

There are also some discrepancies in the quoted wording of the Delaney Amendment as it appears on page 15 and on 16 and I think this should be checked out. If we are talking about the same section and it is the relevant one, I am sure that it did include reference to ingestion by man or animal.

For the summary of my own contribution:

"Dr. Lederberg explored some of the dilemmas and uncertainties that attend efforts at rational cost-risk-benefit analysis. These include value and economic judgments about the price of life and health, conflicts between private freedoms and public safety, and about the redistribution of goods appropriate to public health objectives. The secondary effects of rigorous regulation through the discouragement of research and investment in new products and through the maintenance of monopolies for past products also need to be measured for risk-benefit analysis. On the technical side the population effects of toxic compounds administered at low doses need more empirical research, but more emphasis still should be placed on the biochemical mechanisms of toxicity than on repetitious rote trials.

Since much of the problem of drug regulations stems from the suboptimal use of approved products, new approaches should be sought to help encourage the more rapid development and evaluation of new agents in the hands of responsible prescribers, even if this may mean a limitation of the market for a period of time. (Many of these remarks are inapt for the additive problem.)

With specific reference to the Delaney Amendment, Dr. Lederberg voiced theoretical objections to its language, if this were to be applied blindly; however, he did not criticize its actual application, particularly in the light of recent interpretations by FDA, and he doubted that repeal would serve any useful purpose. Instead he asked for more cogent scientific information that would allow more meaningful extrapolation of animal data to man as a necessary

basis for more refined regulation and if need be legislation."

Sincerely yours,

ORIGINAL SIGNED BY
JOSHUA LEDERBERG

Joshua Lederberg
Professor of Genetics

JL/rr
Enclosures